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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,369	08/17/2001	David A. Estell	GC626-2	4880

5100 7590 04/19/2004

GENENCOR INTERNATIONAL, INC.
 ATTENTION: LEGAL DEPARTMENT
 925 PAGE MILL ROAD
 PALO ALTO, CA 94304

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,369

Applicant(s)

ESTELL ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 10, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-33 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 16-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 5-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

The amendment filed February 10, 2004 is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 5-7 and 11-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Aebersold et al (US 2002/0076739).

Aebersold et al disclose a method for determining the absolute amounts of specific proteins (target biopolymer) in a complex mixture. Aebersold et al disclose adding a known amount of internal standard (analog), one for each specific protein in the mixture to be quantified, is added to the sample to be analyzed (p. 3, paragraph 0032).

Aebersold et al disclose that the internal standard is an affinity tagged peptide that is identical in chemical structure to the affinity tagged peptide to be quantified except that the internal standard is differentially isotopically labeled, either in the peptide or in the affinity tag portion, to distinguish it from the affinity tagged peptide to be quantified (p. 3, paragraph 0032). Aebersold et al also disclose that isotopic label may be an isotopically stable isotope such as ^2H , ^{13}C , ^{15}N or ^{18}O (p. 4, paragraph 37). Aebersold

et al disclose that the sample can be a cell or tissue lysate (paragraph 32) or cell homogenate. Aebersold et disclose digesting the proteins in the mixture with trypsin (fragmenting activity) (p. 7, paragraph 70, p. 19 paragraph 200 and scheme 1). Aebersold et al also teaches subjecting the proteins in the mixture to liquid chromatography and analysis with mass spectrometry (p. 7, paragraph 72, p. 19 paragraph 200 and scheme 1). Aebersold et al discloses that the mass spectrometry measurement readily differentiates between peptides originating from different samples because of the difference between isotopically distinct reagents attached to the peptides. The ratios between the intensities of the differing weight components of these pairs of peaks provide an accurate measure of the amount of the peptides in the original pools because the mass spectrometry intensity response to a given peptide is independent of the isotopic composition (p. 7, paragraph 76).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebersold et al (US 2002/0076739) in view of Chait (US 6,391,649).

See above for teachings of Aebersold et al.

Aebersold et al differ from the instant invention in failing to teach one of said target biopolymer and said analog is enriched in ^{15}N , and the other contains a natural abundance of N isotopes.

Chait et al disclose comparing the levels of proteins present in samples which differ in some respect from each other using mass spectrometry (abstract). Chait et al disclose culturing a first sample in a medium containing a natural abundance of isotopes and a second sample of same biological matter is cultured in a second medium in which the second medium is enriched in isotopes such as nitrogen-15, carbon-13, and oxygen-18 (col. 5, lines 35-58). Chait et al disclose that either medium may be modulated by a microbiological culture such as bacteria (col. 6, lines 15-20,). Chait et al

disclose combining the two sample and treating with a detergent to digest the proteins (fragmenting activity) (Fig. 3, col 6, lines 24-67) then separating the proteins (resolving) and subjecting the proteins to mass spectrometry to identify the proteins. Chait et al disclose that by culturing samples in this manner provides for methods of accurately comparing the levels of ionizable components of biological matter (col 3, lines 40-46) and that determining these levels allows is important in gaining an understanding of biological processes involved in living cells.

It would have been obvious to one of ordinary skill in the art to incorporate enrichment of ^{15}N and natural N isotopes as taught by Chait et al into the method of Aebersold et al because Chait et al teaches the same isotopes as Aebersold et al and also teaches digesting and separating proteins and subjecting them to mass spectrometry. Further, Chait et al shows that that by culturing samples in this manner provides for methods of accurately comparing the levels of ionizable components of biological matter and that determining these levels allows is important in gaining an understanding of biological processes involved in living cells.

Response to Arguments

7. Applicant's arguments filed February 10, 2004 have been fully considered but they are not persuasive.

8. Applicant argues that Aebersold does not disclose an absolute quantity and that according to the current invention, an absolute quantity is determined by using, as a reference, a well-characterized and quantitatively defined compound. In response to applicant's argument that the references fail to show certain features of applicant's

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invention, it is noted that the features upon which applicant relies (i.e., a well-characterized and quantitatively defined compound) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that Aebersold does not disclose an absolute quantity but, at paragraph 0032, compares one state arbitrarily set as a reference and determines quantity based upon the arbitrary comparison. This is not found persuasive because Examiner interprets arbitrary to mean that specified quantities were not recited. However, Aebersold et al teaches that absolute amounts of specific proteins in a complex mixture can be determined and that known amounts of internal standard (analog) are added to the sample (page 3, paragraph 0032, lines 30-44). Therefore, it is the Examiner's position that Aebersold reads on the instantly recited claims.

Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

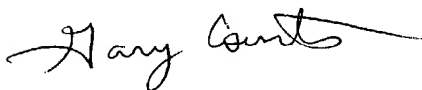
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary W. Counts
Examiner
Art Unit 1641
April 14, 2004



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SUPERVISORY PATENT EXAMINER
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04/16/04